

Drug Shortages: FDA's Role, Triggers, Potentiators, and Buffers

National Academies Webinar Series on Critical Resource Continuity:
Securing Blood, Oxygen, and Saline for Health System Resilience

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CDR Emily Thakur, R.Ph., Team Leader
US Food and Drug Administration

Outline

- FDA's role in working with drug supply
- Triggers: Shocks to the System
- Potentiators: Structural Vulnerabilities
- Buffers: Sources of Resilience

FDA'S ROLE IN WORKING WITH DRUG SUPPLY

Drug Shortage Staff Overview and Mission

Drug Shortage Staff (DSS)

- FDA group that is designated to oversee and facilitate the resolution of all drug shortage situations

Mission

- Prevent, mitigate, and alleviate drug shortages
- Patient and practitioner access to life-saving medications is our priority

Drug Shortage Staff Role

DSS supports FDA's mission of ensuring that safe and effective drugs are available to patients

- Facilitate short-term and long-term strategies
- Coordinate a timely and comprehensive risk/benefit analysis
- Distribute information

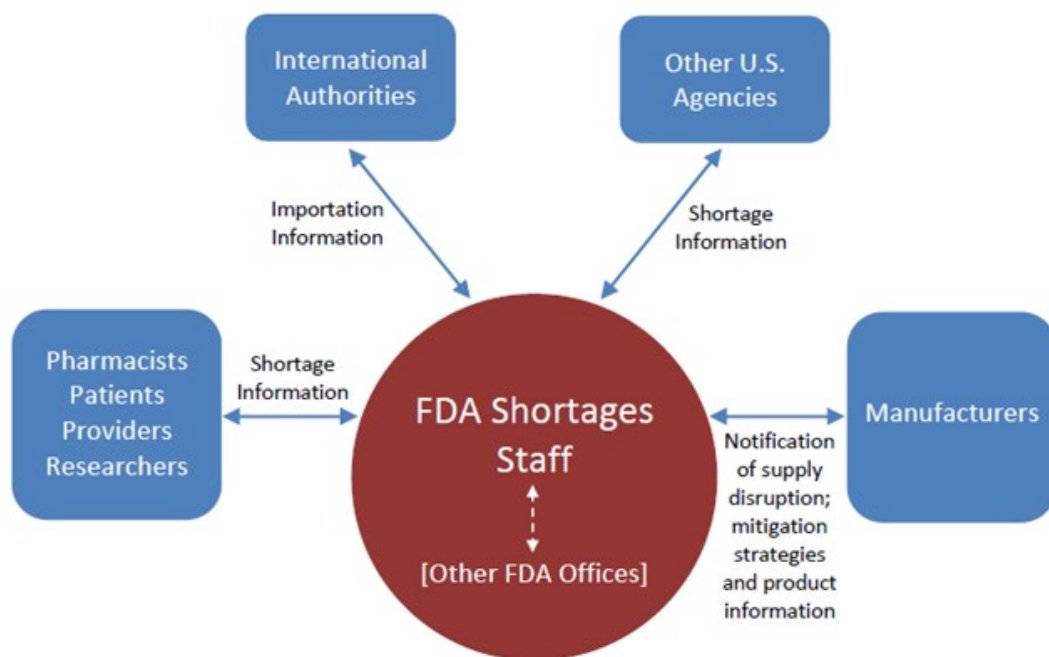
Drug Shortage Staff Role

DSS works with key stakeholders within the FDA:

- Office of New Drugs (OND)
- Office of Pharmaceutical Quality (OPQ)
- Office of Generic Drugs (OGD)
- Office of Compliance (OC)
- Office of Inspections and Investigations (OII) Field Inspectors
- Others

Drug Shortage Staff Role

DSS works with key stakeholders from other government agencies, industry, and the public:



Approach to Prevention and Mitigation

- Prioritize products that are medically necessary
- Risk/benefit analysis
- Maintain availability while minimizing risk
- Work with manufacturers to address problems
- Drug shortages cannot always be prevented

TRIGGERS: SHOCKS TO THE SYSTEM

Causes of Drug Shortages

Quality and Manufacturing Issues

- Sterility
- Particulates
- Crystallization
- Precipitate
- Impurities
- Degradants
- Equipment breakdown

Causes of Drug Shortages

Other Issues

- Discontinuations
- KSM, API, and component supply
- Natural disasters
- Facility damage
- Geopolitical events
- Economic issues
- Increase in demand

POTENTIATORS: STRUCTURAL VULNERABILITIES

Potentiators

- Lack of impacted manufacturer redundancy
- Lack of manufacturers in a market
- Inability of other manufacturers in a market to increase supply
- Hoarding
- Lack of alternate sources of KSM, API, or components
- Regulatory submission and review
- Lack of a risk management plan

BUFFERS: SOURCES OF RESILIENCE

Our Toolbox

- Communicate possible shortage concerns to other suppliers
- Prompt manufacturers to look at supply and demand
- Regulatory flexibility and discretion
- Expedite review of proposals and regulatory submissions
- Expiry extension
- Temporary importation of an unapproved product

Other Buffers

- Multiple manufacturers in a market
- Suitable clinical alternatives
- Safety stock
- Allocation

THANK YOU.

EMILY.THAKUR@FDA.HHS.GOV

DRUGSHORTAGES@FDA.HHS.GOV

